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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,587	03/29/2004	Daniele Pressato	2039-0124PUS2	2626

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EXAMINER

MAIER, LEIGH C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/812,587	Applicant(s) PRESSATO ET AL.	
	Examiner Leigh C. Maier	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 12-15 and 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 16-19 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/031,835.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restriction***

Applicant's election with traverse of Group II, claims 11-19 and 24 in the reply filed on January 21, 2005 is acknowledged. The traversal is on the ground that the subject matter of group I would be uncovered during a search of the group II claims. This is not found persuasive because a complete search for the product is not limited to its most broad form but also requires a search for structural limitations not required in the search for the method. The examiner maintains that the searches for the two separate inventions comprising all their limitations are not coextensive in scope.

Claims 1-10 and 20-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 12-15 are also withdrawn at this time as not corresponding to the elected species.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 appears to recite a method, "the method according to claim 20 ..." However, claim 20 is a product claim and recites no method. Therefore one of ordinary skill would not be

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apprised of the metes and bounds of the claim. Claim 18 depends from claim 17 and is similarly vague and indefinite.

Claim Rejections - 35 USC § 103

Claims 11, 16, 19 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al (EP 341745) in view of Malson et al (US 5,783,691).

The claims are drawn to a method for preventing surgical adhesions of tissue comprising the application of an autocrosslinked (0.5 to 20% crosslinking) derivative of HA to tissues involved in surgery. Dependents further limit the form of the HA, the type of surgery and the extent of crosslinking.

Della Valle teaches autocrosslinked HA, with a 5% crosslinked product exemplified. See abstract and examples 2 and 3. The reference further teaches the use of this product in a variety of forms, such as films, sheets and threads. See page 11, lines 10-20. The reference further states that the articles prepared using the HA products are “similar to those already known and commercially available or described in the literature,” thereby specifically suggesting the use of this product in place of other similar products known in the art. However, the reference is silent regarding the prevention of surgical adhesions.

Malson teaches that HA and crosslinked HA derivatives are known generally to be useful in medical applications, such as prevention of post-operative adhesions. See col 1, lines 19-54. The reference is drawn specifically to HA that is crosslinked through phosphate ester linkages. See col 1, lines 55-62. The reference further teaches the use of this product as a slow-release form of HA, useful for the applications known for HA, per se, and other crosslinked HA

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derivatives. See col 4, lines 10-39. Finally, the reference teaches that this product is superior to other known crosslinked HAs because it introduces fewer “alien” products that may result in immunological or inflammatory reactions. See col 1, lines 43-54.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the Della Valle crosslinked HA products for the prevention of post-surgical adhesions. One of ordinary skill would reasonably expect success in using this product for such prevention because Malson had taught that HA and crosslinked HA derivatives are known to have this utility. The artisan would be further motivated to use this product because it is crosslinked without incorporating into the covalent structure chemicals that could produce undesirable immunological/inflammatory reactions. In the absence of unexpected results, it would further be within the scope of the artisan to prepare and administer the crosslinked HA in any form useful in surgery. It is noted that the examiner finds no definition of “membrane” that would distinguish it from “film” or “sheet.” Regarding the types of surgery, the references do not teach any particular type of surgery. However, claim 24 appears to cover essentially any type of surgery that might be contemplated by one of ordinary skill.

Claims 11, 16, 19 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al (EP 341745) in view of Malson et al (US 5,783,691) and further in view of Matsuda et al (US 5,462,976).

Della Valle and Malson teach as set forth above. The references do not teach the full range of forms recited in claim 19.

Matsuda also teaches that crosslinked glycosaminoglycans, such as HA, have are useful for the prevention of surgical adhesions. See section bridging col 17-18 and examples 19 and 25. The reference further teaches that these crosslinked biopolymers may be prepared in a variety of forms, such as knit, woven or non-woven fabrics, etc. See col 18, lines 48-52.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the Della Valle crosslinked HA material in any form known to be useful for surgical applications with a reasonable expectation of success. Della Valle had specifically taught the preparation of crosslinked HA in the form of threads. In the absence of unexpected results, it would be within the scope of the artisan to further process such threads and prepare the product in the forms suggested by Matsuda.

Claims 11, 16, 19 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al (EP 341745) in view of Malson et al (US 5,783,691) and further in view of Leshchiner et al (US 5,399,351).

Della Valle and Malson teach as set forth above. The references do not teach any specific type of surgery.

Leshchiner also teaches that viscoelastic gels comprising crosslinked biopolymers, such as HA derivatives, have utility for the prevention of post-operative adhesions. See paragraph bridging col 3-4 and col 8, lines 18-27. The reference further teaches "it is well known that adhesion formation between tissues is one of the most common and extremely undesirable complication after almost any kind of surgery." See col 8, lines 28-31.

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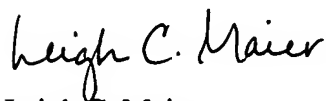
It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the Della Valle crosslinked products to prevent adhesion formation during any type of surgery, as this complication is one known for surgery in general. One of ordinary skill would have a reasonable expectation of success in carrying out this method as set forth above. In the absence of unexpected results with the particular types of surgery recited, it would be within the scope of the artisan to use the product for any known type of surgery with a reasonable expectation of success.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

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Leigh C. Maier
Patent Examiner
February 17, 2006